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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,069	12/04/2003	Carsten Muenk	532792000100	9175

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EXAMINER

WANG, LOUISE Z

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,069	<b>Applicant(s)</b> MUENK ET AL.	
	<b>Examiner</b> Louise Wang	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,7,8 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 9-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7 May 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

The Office acknowledges the receipt of Applicant's election and Amendment filed on 23 September 2005. Claims 16-20 have been cancelled. Applicant elects Group I, claims 1-14, with traverse.

The traversal is on the grounds that there is no undue search burden because subject matter of Group I should encompass the subject matter of Group II, and that the different species are interchangeable.

Applicant's traversal is unpersuasive for the following reasons:

While a search of the prior art for Group I may overlap with that of Group II, they are not co-extensive of each other and thus would represent undue burden on Office resources.

Upon further consideration and review of Applicant's traversal, it appears that Group I and II are distinctly related as combination and subcombination because Group I does not require the particulars of the Group II as claimed for patentability, and Group I has utility by itself or in other combinations (MPEP § 806.05(c)).

The species have different compositions, structures, modes of action, and properties. Accordingly, prior art searches for each species are not coextensive. Since Applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case, the

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species of the first and second cells, viral envelope proteins, CD4 co-receptors, and reporter protein fragments are patentably distinct.

However, this discussion does not extend to the election of cell fusion inhibitor molecule. Applicant's traversal that a cell fusion inhibitor molecule is the objective of the claimed method is persuasive. Therefore, the requirement for the election of a cell fusion inhibitor molecule is withdrawn.

The restriction among the Groups and species that may be used in the claimed methods, except for cell fusion inhibitors, is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending. Claims 3, 7, 8, and 15-20 are nonelected. Claims 1, 2, 4-6, and 9-14 are examined in the instant application and are read with the limitations of the elected species only.

#### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed on 07 May 2004, is attached to the instant Office action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieniasz *et al.* (1997) in view of both Wigley *et al.* (2001) and Isaacs *et al.* (1999).

Claims 1, 2, 4-6, and 9-14 are directed to a method for detecting the presence or absence of cell fusion, comprising contacting a first cell and a second cell, wherein the first cell comprises an alpha fragment of  $\beta$ -gal, HIV *rev*, and *env* gp160; the second cell comprises an omega fragment of  $\beta$ -gal, CD4, and CCR5. When the alpha and omega fragment of  $\beta$ -gal is combined into one functional reporter gene, a chemiluminescent signal of cell fusion is emitted.

Bieniasz *et al.* teaches a 293T cell co-expressing CD4-CCR5-reporter gene and a second 293T cell expressing envelope protein (page 2600, left column, Results).

Bieniasz *et al.* does not teach the complementation of the alpha and omega fragment of  $\beta$ -gal, which emits a chemiluminescent signal of cell fusion, or the additional expression of HIV *rev* on the first cell.

Wigley *et al.* teaches an *in vivo* alpha-complementation fusion system based on structural complementation of the alpha and omega fragment of  $\beta$ -gal. See entire document. Wigley *et al.* specifically teaches the diverse application of the system in the study of fundamental biological processes, which encompasses cell fusion.

Isaacs *et al.* teaches that inside a cell, transcription depends on expression of the HIV-1 auxiliary protein Rev for *env* mRNA export (page 57, Results).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the assay in Bieniasz *et al.* with the additional features suggested by Isaacs *et al.* and Wigley *et al.*, as stated above, for the purpose of a better mimic of the actual fusion stage during HIV infection. One skilled in the art would have been motivated to make the above adaptations to increase the reliability of a cell fusion assay with a reasonable expectation of success. Thus, the instant invention is obvious over Bieniasz *et al.* in view of both Wigley *et al.* and Isaacs *et al.*

#### **Remarks**

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.  
Patent Examiner  
03 November 2005



**JEFFREY STUCKER**  
**PRIMARY EXAMINER**